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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,235	01/04/2005	Jurgen Eitenmuller	04-670	5100
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EXAMINER				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,235

Applicant(s)

EITENMULLER ET AL.

Examiner

ALIREZA NIA

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/003)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1, 2, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fiore US 3,675,641, that teaches the invention as claimed.**

3. With respect to claims 1, 2, 7, and 8, Fiore teaches a proctoscope 10 comprising a hollow-cylindrical body 11 (col. 2, lines 64, 65, 67-68) having a tapering (col. 3, lines 4-6) at a distal end portion at 13 wherein the body has a hole to form an operation window 13, an opening at the other end 14 (col. 3, lines 4-6), a handle portion 23, means for illuminating 24, and lighting means 25 directed onto the operation window 13 (col. 4, lines 24-26 and 44-50) wherein the operation window is formed as a cut-out in an outer wall of the proctoscope body 11 such that it extends into the tapering distal end portion at 13 (figure 1), and wherein the operation window 13 is formed as a cut-out 13 in the hollow-cylindrical proctoscope body 11 (at its distal end in the lateral direction) and in the tapering distal end portion (figure 1). Fiore also teaches an obturator 22 for insertable cooperation with the proctoscope body 11 that when the obturator 22 is inserted into the proctoscope body 11 at least partially closes off the operation window 13 and the obturator 22 has a tongue-like closure portion 21 (col. 3, lines 56-61 and figure 1). Further, Fiore teaches the handle portion 23 at the opening end 14 of the proctoscope body 11 where the

handle 23 is angled with respect to the proctoscope body 11 and forming a hollow space 30 (col. 5, lines 29-48, figure 1).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morinaga US 5,570,692.

6. Morinaga teaches a proctoscope 10 comprising a hollow-cylindrical body 12 having a tapering at a distal end portion 14, an opening at the other end 16 and a handle portion 18, wherein the body has a hole to form an operation window 20 formed as a cut-out 20 (col. 2, lines 23-33 and fig. 1), means for illuminating 40 (col. 2, lines 55-58) comprising lighting means 42 (col. 2, line 59) and means for detecting vessels by means of sensors 22 provided in the body 12 (col. 2, lines 33-37), wherein the operation window 20 is formed in an outer wall of the body 12 (col. 2, line 33 and fig. 1). Morinaga also teaches that operation window 20 opens a free hole area of 350 to 450 mm² in the outer wall of body 12 (col. 3, line 23). It is further taught by Morinaga that the sensor 22 is an ultrasound sensor installed in a wall portion of the body 12 adjacent to the operation window 20 (col. 3, lines 23-30), wherein sensor 22 is connected to vessel detection electronics 62 outside the casing of the body 12 (col. 3, lines 48-52). Moreover, the handle 18 is taught by Morinaga to be a grip (col. 2, line 32) being angled with respect to the

body 12 (fig. 1) forming a hollow space 5 (fig. 3) for the passage of supply lines 4 (col. 3, lines 35-40 and fig.1) and indicating a circumferential position (col. 2, lines 32-33).

7. With respect to the recitation, “the operation window is formed as a cut-out in the hollow-cylindrical proctoscope body and in the tapering distal end portion” in lines 12-14 of claim 1, although Morinaga does not positively disclose the cut-out in the hollow-cylindrical proctoscope body to be formed in the tapering distal end portion, it would have been obvious to one of ordinary skill in the art at the time of the invention to have increased the size of the cut-out 20 in the longitudinal direction toward the tapered distal end such that the cut-out would have extended further into the tapering distal end portion as desired in order to have provided a larger opening on the side of the proctoscope, since it has been held that, “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05 II A). It would have also been obvious to one of ordinary skill in the art at the time of the invention to have arranged the cut-out 20 at the tapering distal end portion of the proctoscope body portion, since it has been held that rearranging parts of an invention involves only routine skill in the art, In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (MPEP 2144.04 VI C).

8. Claims 3, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore US 3,675,641 in view of Moore et al. US 3,417,746.

9. Fiore discloses the invention as discussed.

10. However, Fiore fails to positively disclose an obturator having a handle portion protruding out of the opening of a proctoscope. Fiore also fails to positively disclose a light-permeable reflector element in the tapering end portion of the proctoscope.

11. Moore teaches an analogous proctoscope comprising an obturator having a handle portion 42 protruding out of the opening of the proctoscope (col. 3, lines 34-37), and a light-permeable reflector element 59 in the tapering end portion of the proctoscope (col. 4, lines 9-18), resulting in an improved instrument having disposable parts that during use they would prevent any contact while efficiently illuminating the area examined or worked on (col. 1, lines 39, 51-52).

12. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the proctoscope of Fiore with the above limitations as taught by Moore in order to have provided an improved instrument (a sigmoidoscope) having disposable parts that during use they would prevent any contact while efficiently illuminating the area examined or worked on by a surgeon.

13. Claims 5, 6, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore US 3,675,641 in view of Morinaga US 5,570,692.

14. Fiore discloses the invention as discussed. Fiore further discloses closing the operation window 13 in the proctoscope body 11 with the obturator 21,22 and inserting the proctoscope body 11 into a patient's anus.

15. However, Fiore fails to positively disclose a the operation window opens up to a free hole area of 350 to 400 mm² in the outer wall of the proctoscope. Fiore also fails to positively disclose the sensor comprises a duplex or ultrasound sensor which is permanently installed in a

wall portion of the proctoscope body adjacent to the operation window, wherein said sensor is connected to vessel detection electronics provided outside the casing of the proctoscope body. Fiore also fails to positively disclose detecting blood vessels by means of ultrasound Doppler sonography and orienting the proctoscope body in reaction to the detection.

16. Morinaga teaches an analogous proctoscope comprising a probe hole area of 350 to 400 mm² (126 mm² to 1141 mm²) (col. 2, lines 41-43), an ultrasound sensor 22 capable of Doppler effect (col. 2, lines 35 and col. 3, lines 23-40) connected to vessel detection electronics 60 (col. 3, lines 41-53) and its method of use in an operation (col. 3, col. 4), resulting in an improved an ultrasonic Doppler blood flow detector and its method of use for hemorrhoid artery ligation through a ligation hole (col. 1, lines 7-9 et seq. lines 64-65).

17. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the proctoscope of Fiore with the above discussed limitations as taught by Morinaga in order to have provided an improved ultrasonic Doppler blood flow detector and its method of use for hemorrhoid artery ligation through a ligation hole, facilitating an efficient and accurate diagnosis of Crohn's inflammatory bowel diseases and the like.

18. Claims 1, 2, 3, 5-8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaji 6,142,931 in view of Morinaga US 5,570,692.

19. Kaji discloses a proctoscope 1 comprising a proctoscope body 2,3 which is hollow-cylindrical and is to be inserted into a patient's anus, said proctoscope body 2,3 having a tapering at a distal end portion (figs. 1A,11A), an opening at the other end (figs. 1A,11A) and a handle portion 9,71,72 (fig. 12), wherein the proctoscope body 2,3 has a hole 31,32,33 to form an operation window 33 toward a free interior space of the proctoscope body 2,3, wherein the

operation window 33 is formed in an outer wall 2,3 of the proctoscope body 2,3 such that it extends into the tapering distal end portion (figs. 1A,11A), and wherein the operation window 33 is formed as a cut-out 31,32 in the hollow-cylindrical proctoscope body 2,3 and in the tapering distal end portion (figs. 1A,11A, col. 7, lines 20-67, cols. 8-16, lines 1-67). Kaji further discloses a manually operable obturator 4 (figs. 11A,12) for insertable cooperation with the proctoscope body 2,3 and is adapted to the free interior space such that, when the obturator 4 is inserted into the proctoscope body 2,3 through the opening, a closure portion 31,4 (fig. 11A) of the obturator at least partially closes off the operation window 33 (figs. 11A,12). Kaji further discloses the obturator 4 has a handle portion 85,86,90 which in the inserted state protrudes out of the opening (figs. 11A,12), and the closure portion (fig. 12) is designed as a tongue-like extension of an essentially cylindrical obturator casing 4 (figs. 11A,12). Kaji further discloses the handle portion 9,71,72 is designed as a grip 9 at the opening end of the proctoscope body 2, the grip being at an angle with respect to the proctoscope body 2.

20. However, Kaji fails to positively disclose means for illuminating the operation window and/or means for detecting vessels by means of sensors to be provided in the proctoscope body. Kaji also fails to positively disclose the sensor comprises a duplex or ultrasound sensor which is permanently installed in a wall portion of the proctoscope body adjacent to the operation window, wherein said sensor is connected to vessel detection electronics provided outside the casing of the proctoscope body. Kaji also fails to positively disclose detecting blood vessels by means of ultrasound Doppler sonography and orienting the proctoscope body in reaction to the detection. Kaji also fails to positively disclose the grip forming a hollow space for the passage of supply lines for the illuminating and/or vessel detection means and further indicating a

circumferential position of the vessel detection means on the proctoscope body, wherein the means for illuminating comprises lighting means directed onto the operation window provided in the tapering end portion.

21. Morinaga teaches an analogous proctoscope comprising means for illuminating 40 (col. 2, lines 55-58) comprising lighting means 42,48 (col. 2, line 59) capable of being directed onto the operation window 20 and means for detecting vessels by means of sensors 22 provided in the body 12 (col. 2, lines 33-37). Morinaga also teaches a probe hole area of 350 to 400 mm² (126 mm² to 1141 mm²) (col. 2, lines 41-43), an ultrasound sensor 22 capable of Doppler effect (col. 2, lines 35 and col. 3, lines 23-40) connected to vessel detection electronics 60 (col. 3, lines 41-53). Morinaga further teaches a handle 18 being a grip (col. 2, line 32) and being angled with respect to the body 12 (fig. 1) forming a hollow space 5 (fig. 3) for the passage of supply lines 4 (col. 3, lines 35-40 and fig.1) and indicating a circumferential position (col. 2, lines 32-33), and their method of use in an operation (col. 3, col. 4), resulting in an improved an ultrasonic Doppler blood flow detector and its method of use for hemorrhoid artery ligation through a ligation hole (col. 1, lines 7-9 et seq. lines 64-65).

22. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the proctoscope of Kaji with the above discussed limitations as taught by Morinaga in order to have provided an improved ultrasonic Doppler blood flow detector and its method of use for hemorrhoid artery ligation through a ligation hole, facilitating an efficient and accurate diagnosis of Crohn's inflammatory bowel diseases and the like.

23. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaji 6,142,931 in view of Morinaga US 5,570,692 further in view of Moore et al. US 3,417,746.

24. Kaji in view of Morinaga discloses the invention as discussed above. However, Kaji in view of Morinaga fails to positively disclose a light-permeable reflector element in the tapering end portion of the proctoscope.

25. Moore teaches an analogous proctoscope comprising an obturator having a handle portion 42 protruding out of the opening of the proctoscope (col. 3, lines 34-37), and a light-permeable reflector element 59 in the tapering end portion of the proctoscope (col. 4, lines 9-18), resulting in an improved instrument having disposable parts that during use they would prevent any contact while efficiently illuminating the area examined or worked on (col. 1, lines 39, 51-52).

26. It would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the device of Kaji in view of Morinaga with the above limitations as taught by Moore in order to have provided an improved instrument (a sigmoidoscope) having disposable parts that during use they would prevent any contact while efficiently illuminating the area examined or worked on by a surgeon.

Response to Amendment

27. The amendment to claim 1 and the cancellation of claim 4, in the response filed on January 23rd, 2008 is acknowledged.

28. Currently, claims 1-3 and 5-11 are pending in the application.

Response to Arguments

29. Applicant's arguments with respect to claim 1, as being anticipated under 35 U.S.C. 102(b) by Morinaga 5,570,692 have been considered but are moot in view of the new ground(s) of rejection.

30. Applicant's arguments with respect to claim 1 as rejected under 35 U.S.C. 102(b) as being anticipated by Fiore 3,675,641, filed January 23rd, 2008, have been fully considered but they are not persuasive.

31. With respect to claim 1, the Applicant has argued that *"Furthermore, it is clear that the amended claim cannot be rejected over the Fiore reference as the (slightly conical) body does not have a window but is open at the end thereof"*. The examiner respectfully disagrees with Applicant. To rebut Applicant's argument above, the examiner points out that claim 1 recited "wherein the operation window is formed in an outer wall of the proctoscope body such that it extends into the tapering distal end portion" lines 10-12. Clearly, Fiore's reference positively discloses the operation window 13 to be formed in the tapered outer wall of the proctoscope body 11 and already extending into the tapering distal end portion (extending in the lateral direction of the tapered distal tip encompassing the circumferential area of the tapered distal end portion, see fig. 1). Thus, in light of examiner's response above, and in view of the amendment to claim 1, clearly Fiore's reference also teaches the operation window 13 is formed as a cut-out 13 in the hollow-cylindrical proctoscope body 11 and in the tapering distal end portion (fig. 1). Therefore, the rejection under 35 U.S.C. 102(b) of claim 1 as being anticipated by Fiore 3,675,641 has been maintained by the examiner.

Conclusion

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALIREZA NIA whose telephone number is (571)270-3076. The examiner can normally be reached on Mo.-Fri.-7:30 AM-5:00 PM EST-Alternate Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair->

Art Unit: 3739

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/A. N./

Examiner, Art Unit 3739

Alireza Nia

May 12th, 2008

/Linda C Dvorak/

Supervisory Patent Examiner, Art Unit 3739